510(k) SUMMARY

MAR 07 2007

SUBMITTED BY: BECTON, DICKINSON AND COMPANY
7 LOVETON CIRCLE
SPARKS, MD 21152
Phone: 410-316-4905
Fax: 410-316-4499

CONTACT NAME: Dainelle N. Clark

DATE PREPARED: March 6, 2007

DEVICE TRADE NAME: BD Directigen™ EZ Flu A+B Test

DEVICE COMMON NAME: Influenza virus serological reagents

DEVICE CLASSIFICATION: 21 CFR§866.3330

PREDICATE DEVICES:
Viral Cell Culture
Direct fluorescent antibody (DFA)
BD Directigen™ Flu A+B Test
Binax NOW® Influenza A&B Test

INTENDED USE:

The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates, nasopharyngeal swabs and throat swabs of symptomatic patients. The BD Directigen EZ Flu A+B test is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture because negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

Performance characteristics for Influenza B using nasopharyngeal swabs (NPS) were established primarily with retrospective, frozen specimens. Users may wish to establish the sensitivity of this test for Influenza B using fresh nasopharyngeal swab specimens.

DEVICE DESCRIPTION:

The BD Directigen EZ Flu A+B test is a chromatographic assay to qualitatively detect influenza A and B viral antigens in samples processed from respiratory specimens. When specimens are processed and added to the test device, influenza A or B viral antigens bind to anti-influenza antibodies conjugated to visualizing particles in the corresponding

A and B test strips. The antigen-conjugate complex migrates across the test strip to the reaction area and is captured by the line of antibody on the membrane. A positive result for influenza A is visualized as a reddish-purple line at the Test "T" position and the Control "C" position in the BD Directigen EZ device Flu A read window. A positive result for influenza B is visualized as a reddish-purple line at the Test "T" position and the Control "C" position in the BD Directigen EZ device Flu B read window.

DEVICE COMPARISON:

The BD Directigen EZ Flu A+B test was compared to viral cell culture, direct fluorescent antibody (DFA) tests, the BD Directigen Flu A+B test (K001364) and the Binax NOW Influenza A&B test (K053126). Comparison testing of the BD Directigen EZ A+B test and viral cell culture did not exhibit any new issues associated with the safety and effectiveness of the product when using nasopharyngeal swab specimens. The studies demonstrate that the BD Directigen EZ A+B test is substantially equivalent[1] to the predicate device, viral cell culture.

SUMMARY OF PERFORMANCE DATA:

CLINICAL STUDIES

New performance characteristics of the BD Directigen EZ Flu A+B test were established in a geographically diverse multi-center study to support the addition of the nasopharyngeal swab specimen type to the intended use of this device.

Clinical Performance

The performance characteristics of the BD Directigen EZ Flu A+B test as compared to viral cell culture were determined using 456 prospective nasopharyngeal swab specimens. The sensitivity and specificity of the BD Directigen EZ A+B test for influenza A were 90.7% (146/161) and 93.2% (275/295), respectively. For influenza B, the sensitivity and specificity were 100.0% (1/1) and 100.0% (455/455), respectively. To augment the study with an adequate number of positive samples for influenza B, 59 retrospective nasopharyngeal swab specimens were tested with the BD Directigen EZ Flu A+B test and compared to viral cell culture. The positive and negative agreement of the BD Directigen EZ A+B test for influenza A with the retrospective nasopharyngeal swab specimens were 85.7% (6/7) and 96.2% (50/52). The positive and negative agreement for influenza B with the retrospective nasopharyngeal swab specimens were 74.4% (32/43) and 100.0% (16/16), respectively.

Overall performance of the BD Directigen EZ Flu A+B test is substantially equivalent[1] to viral cell culture that was in use prior to May 28, 1976.

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or

reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Dainelle N. Clark
Regulatory Affairs Specialist
BD Diagnostics Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

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Re: k063689
Trade/Device Name: BD Directigen™ EZ Flu A+B Test
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class II
Product Code: GNX
Dated: December 11, 2006
Received: December 12, 2006

Dear Ms. Clark:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

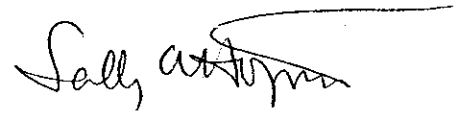
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: k 063689

Device Name: BD Directigen™ EZ Flu A+B Test

Indications for Use:

The BD Directigen™ EZ Flu A+B test is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal washes/aspirates, nasopharyngeal swabs and throat swabs of symptomatic patients. The BD Directigen EZ Flu A+B test is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. All negative test results should be confirmed by cell culture because negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions.

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Prescription Use √ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k 063689